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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/990,187      | 11/20/2001  | Sundeep Dugar        | 219002029300        | 1222             |

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EXAMINER

HABTE, KAHSAY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/990,187

Applicant(s)

DUGAR ET AL.

Examiner

Kahsay Habte, Ph. D.

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1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Restriction/Election***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-13 (in part), 15-37 (in part), 39 (in part) and 42-44 (in part), drawn to diazepine compounds ( $l=1$ ,  $k=2$  or  $l=2$ ,  $k=1$  and  $Z^1$  is N), classified in class 540, subclass various.
  - II. Claims 1-12 (in part), 14-37 (in part), 39 (in part) and 42-44 (in part), drawn to azepine compounds ( $l=1$ ,  $k=2$  or  $l=2$ ,  $k=1$  and  $Z^1$  is C), classified in class 540, subclass various.
  - III. Claims 1-12 (in part), 14-37 (in part), 39 (in part) and 42-44 (in part), drawn to azetidine compounds ( $l=k=0$ ), classified in class 540, subclass various.
  - IV. Claims 1-13 (in part), 15-39 (in part), and 42-44 (in part), drawn to piperazine compounds ( $l=k=1$  and  $Z^1$  is N), classified in class 544, subclass various.
  - V. Claims 1-12 (in part), 14-39 (in part), and 42-44 (in part), drawn to piperidine compounds ( $l=k=1$  and  $Z^1$  is C), classified in class 546, subclass various.
  - VI. Claims 1-14 (in part), 14-37 (in part), 39 (in part) and 42-44 (in part), drawn to azole and diazole compounds ( $l=0$ ,  $k=1$  or  $l=1$ ,  $k=0$  and  $Z^1 = C$  or N), classified in class 548, subclass various.

VII. Claims 40-41, drawn to complex composition compounds, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons: Groups I-VI are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of  $Z^1$ , **I** and **k** in the compound formula do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. Groups I-VI are drawn compounds, simple composition and use, are different from Group VII that are drawn to complex composition. Group II has an additional ingredient (corticosteroid) that is not present in Group I. This is because of the possibility of synergistic interaction, which is usually the purpose of the complex composition in the first place. Groups I (diazepines) are different from Groups II-VI, because they have 2 nitrogens in the seven-membered ring and this feature is not present in Groups II-VI. Group II (azepines) is different than Groups I, III-VI, since it contains a nitrogen in a seven-membered ring. Group III is drawn to azetidine (one N in a four-membered ring) that is not present in Groups I-II and III-VI. Group IV is drawn to piperazines (2 nitrogens in a six-membered ring) that is not present in Groups I-III and V-VI. Group V is drawn to piperidines (one nitrogen in a six-membered ring) and this feature is not present in Groups I-IV and VI. Group VI is drawn to azoles and diazoles (five-membered ring with one or two nitrogens) and is different than Groups I-V. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support

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separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Ms. Kate Murashige on Jan. 28, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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**Conclusion**

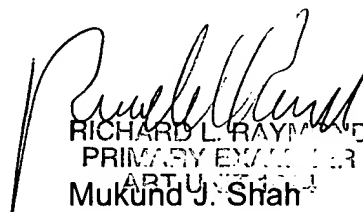
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



RICHARD L. RAYMOND  
PRIMARY EXAMINER  
ART UNIT 1624

Mukund J. Shah  
Supervisory Patent Examiner  
Art Unit 1624

KH  
February 5, 2003